

Managing risks to the public: appraisal guidance

June 2005



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HM Treasury contacts

This document can be accessed from the Treasury Internet site at:

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For further information on the Treasury and its work, contact:

Correspondence and Enquiry Unit
HM Treasury
1 Horse Guards Road
London
SW1A 2HQ

Tel: 020 7270 4558

Fax: 020 7270 4861

E-mail: ceu.enquiries@hm-treasury.gov.uk

CONTENTS

		Page
Foreword	Managing risks to the public: appraisal guidance	3
Chapter 1	Introduction and overview	5
Chapter 2	Government intervention	9
Chapter 3	Options for risk management	15
Chapter 4	Appraising costs and benefits	21
Chapter 5	Developing and evaluating implementation strategies	31
Annex A	Concern assessment tool	33
Annex B	Government's Principles of managing risk to the Public	45
Annex C	CBA and QALY approaches compared	47
Annex D	Glossary	53
Bibliography		55

FOREWORD MANAGING RISKS TO THE PUBLIC: APPRAISAL GUIDANCE

This guidance is designed to help policy makers address certain risks that the public faces, and also its perceptions of risk. Government has a role to protect and assure the public, which includes taking cost effective action to reduce risk, and to provide accurate and timely information about risk.

The approach contained here attempts to incorporate and point to good practice in the management, communication and economic valuation of risk. These are still developing areas of expertise. Over time, it is hoped that a more complete methodology will emerge, building on the extensive academic research that is currently underway. The Treasury is very grateful for the significant contributions to the development of this guidance that have been made across government and academia, in particular to those who contributed to and commented on the consultation draft.

One objective of this guidance is to achieve greater consistency and transparency in government decision-making. It aims to achieve this by recommending greater use of evidenced based values of preventing fatality, and other harms, and supports further studies to inform our understanding of the appropriate economic values to use given differences in context. More widespread use of evidence-based values would help to achieve greater consistency in decision making, increasing (in certain areas) risk management activity, and preventing or curbing it in areas where the benefits are not justified by the costs.

Cost benefit analysis (CBA) is an important tool that can provide an assessment of how much society wants devoted to reducing the risk of fatalities and other harms, given its limited resources and competing demands. Both CBA and cost effectiveness analysis can help decide where and how best to deploy its resources in reducing risk and preventing harm. Government needs to take action that addresses risks in a proportionate, consistent way, based on the evidence of what is most cost effective.

This guidance also recommends that, alongside the technical analysis of options available to reduce risk, decision makers should take explicit steps to involve the public: to understand what they are concerned about and why, and to communicate good information about risk, targeted to the needs of the audiences involved.

Finally, these various tools and techniques still require good judgment to determine the most appropriate action for government and society to take given the risks they face.



Nick Stern - Second Permanent Secretary to the Treasury and Head of the Government Economic Service

INTRODUCTION AND OVERVIEW

INTRODUCTION

Green Book

1.1 This document provides guidance for developing and assessing proposals that affect the risk of fatalities, injury and other harms to the public. It supplements Treasury guidance *Appraisal and Evaluation in Central Government* (the Green Book)¹, which sets out the general approach to carrying out options' appraisal (combined with cost benefit analysis) of all government intervention. This is a requirement for all expenditure and of all new policy actions which may have an impact on businesses, charities, the voluntary or rest of the public sector.²

1.2 The Green Book discusses risk and uncertainty in general terms, but not specifically risks to the public.³ In addition, the Treasury's Orange Book also provides more general guidance on risk management.⁴ This supplementary guidance applies both to proposals which contain elements that relate to public health and safety and those that are primarily concerned with such issues. It supersedes paragraphs 26-33 of Annex 2 of the Green Book.

1.3 The guidance contains a tool (see Appendix A) to help structure and make explicit the assessment of concerns that may exist about risks of fatality and harm, which is a strand of decision-making where there is currently little extant cross-government guidance. In other areas, the text points to articles and existing guidance.

Risk principles

1.4 The Principles of Managing Risks to the Public were published on 12 September 2003. Annex B provides a fuller description but in summary they are:

- **openness and transparency** - Government will be open and transparent about its understanding of the nature of risks to the public and about the process it is following in handling them;
- **involvement** - Government will seek wide involvement of those concerned in the decision process;
- **proportionality and consistency** - Government will act proportionately and consistently in dealing with risks to the public;
- **evidence** - Government will seek to base decisions on all relevant evidence; and,
- **responsibility** - Government will seek to allocate responsibility for managing risks to those best placed to control them.

¹ See <http://www.hm-treasury.gov.uk/greenbook>.

² The government requires in these circumstances that a Regulatory Impact Assessment is carried out. See RIA Guidance: <http://www.cabinetoffice.gov.uk/regulation/ria>.

³ See pages 28-34, Chapter 5, <http://greenbook.treasury.gov.uk/chapter05.htm#introduction> and Annex 4 on risk and uncertainty in the Green Book, <http://greenbook.treasury.gov.uk/annex04.htm>.

⁴ 'Management of Risk – Principles and Concepts' see http://www.hm-treasury.gov.uk/documents/public_spending_and_services/audit_and_accounting/pss_aud_risk04.cfm.

OBJECTIVES

1.5 The main aims of this guidance are to:

- discuss the relative merits and disadvantages of generic options available to government, where risk to the public is of concern;
- provide greater clarity and transparency in the overall decision-making process in this area, by providing a structured process to evaluate public concerns and identify potential policy options;
- promote consistency and proportionality in decision-making, to achieve a more efficient allocation of resources, aligning government's decisions to spend and regulate with the benefits to society. Part of these benefits can be valued by estimating individuals' willingness to pay for risk reduction and prevention;
- consolidate various techniques, including cost benefit and cost utility analysis, as well as risk management, into a single set of guidance.

1.6 The main outputs envisaged from applying this guidance are:

- improved analysis of individual policies ("bottom up");
- improved strategies for risk reduction and prevention ("top down"), across government and within individual departments, agencies and non-departmental public bodies (NDPBs);
- the encouragement of more collaborative approaches across government and across professional disciplines; and,
- improved consistency and transparency in policies, consultation arrangements and communication strategies.

1.7 The ultimate outcome desired from applying this guidance is an overall improvement in social welfare, through more cost effective reductions in risk, and more consistent allocations of government resources to risk reducing measures.

SCOPE AND LIMITATIONS

Scope

1.8 This guidance covers both government expenditure and strategic policy development (including regulation). It is aimed at policy makers, economists, risk and communication specialists, scientists and social researchers – particularly those new to this field – and applies to central government departments, executive agencies and non-departmental government bodies⁵. It sets out broad guidance, but does not provide all the detail on specific techniques. The text points to further information where available. It is not designed to help in deciding the appropriate intervention for a specific, known individual, but to help develop policy responses where whole groups or populations are at risk. It should not be used for compensation claims.

⁵The scope of the application of the Green Book and its supplementary guidance is set out in a Dear Accounting Officer letter (27 February 2003). See <http://www.hm-treasury.gov.uk/media/89E/1B/dao0503.pdf>.

Legal frameworks

1.9 In the UK, there are various legal frameworks that affect the management of risks, which in general require some test of proportionality – that the costs of risk reduction are justified by the benefits. Various methodologies have been devised to interpret these legal frameworks and to apply them in practice. These include:

- health and safety legislation, which require that risks, be reduced ‘as low as is reasonably practicable’ (ALARP). The legal interpretation of this is that a risk reduction measure should be implemented unless there is a ‘gross disproportion’ between the cost of a control measure and the benefits of the risk reduction that will be achieved. Furthermore, the interpretation is that this test should be applied at all risk levels, although in practice regulators may apply decision boundaries.⁶
- other proportionality principles used in UK and European legislation include ALARA (‘as low as reasonably achievable’), BPM (‘best practicable means’), BPEO (‘Best Practicable Environmental Option’), and BAT (‘Best Available Techniques’). Each principle is distinctive but all involve a trade-off between the risk incurred and the effort involved in reducing it. The guidance set out here is not intended to replace existing statutory requirements, which will need to be understood and recognised during the appraisal.

OVERVIEW

Steps to take in the appraisal process

1.10 There are a number of generic steps that will need to be taken in the appraisal process. These are set out below and discussed in detail in the guidance.

Chapter 2

1. Consider if there are good prima facie reasons for government intervention (e.g. market failures or equity issues that should be addressed);
2. Carry out an expert risk assessment;
3. Carry out an assessment of public concern (Annex A can be used);
4. Consider the extent of public involvement that may be required during the appraisal and decision-making processes;
5. Develop the decision-making process (including how to involve the public) and make this publicly available;

Chapter 3

6. Consider the options available for addressing the hazards and risks, and the concerns identified. Develop options which address the reasons for intervention, the specific risks and hazards, and the concerns identified in steps 1-3;

⁶ Reducing Risks Protecting People, HSE 2001, HSE books, ISBN 07176 2151 0 (<http://www.hse.gov.uk/dst/r2p2.pdf>)

Edwards v The National Coal Board (1949) 1 All ER 743

The Court of Appeal in Regina v Board of Trustees of the Science Museum (1993) 1 WLR 1121 (page 1177)

Chapter 4

7. Assess the monetary costs and benefits of each option, expressing these within ranges of uncertainty;
8. Assess the non-monetary advantages and disadvantages of each option (and consider other non-monetary issues as well);

Chapter 5

9. Develop an implementation plan, taking the best options in terms of monetary and non-monetary considerations, and developing an affordable, viable plan of action. Explain the basis of decisions and make this publicly available; and,
10. Implement, monitor and evaluate the implementation plan.⁷

Definitions

‘Hazard’ is used throughout this document to mean specifically the potential to cause harm.

‘Risk’ is the likelihood, measured by its probability, that a particular event will occur.⁸

Both hazards and risks are often subject to ‘uncertainty’. Uncertainty is ‘the condition in which the number of possible outcomes is greater than the number of actual outcomes and it is impossible to attach probabilities to each possible outcome.’⁹ For instance, the harmful effects of a hazard may be only estimated within a certain range; and the probability of a harm occurring may not be known.

⁷ It is worth repeating here the guidance contained in the Green Book: “appraisals are often iterated a number of times before their proposals are implemented in full. Therefore the stages set out ... may be repeated, and they may not always be followed sequentially”. See paragraph 2.4, <http://greenbook.treasury.gov.uk/chapter02.htm#processfor>

⁸ For a full technical distinction, see pages 5-6 of Reducing Risks, Protecting People HSE which defines ‘a hazard as the potential for harm arising from an intrinsic property or disposition of something to cause detriment, and risk as the chance that someone or something that is valued will be adversely affected in a stipulated way by the hazard.’

⁹ This definition is taken from the Green Book, Appraisal and Evaluation in Central Government. HM Treasury (2003).

GOVERNMENT INTERVENTION

REASONS FOR GOVERNMENT INTERVENTION

2.1 The first step in an appraisal is to consider whether there are good reasons for government intervention. In the context of managing risks, there may be ‘market failures’ or other socio-economic problems that may make government action worth considering.

Market failures

2.2 From an economic perspective, the market, left to its own devices, will often work to produce the most socially optimal outcomes. However, there can be significant market failures, which are relevant in this context:

- **information problems** - individuals often do not have good information about risk, or the time, willingness or ability to assimilate it and act upon it all the time (e.g. new technologies or personal behaviours that may be detrimental to health);
- **externalities** – individuals and businesses may create risks that affect people other than themselves, which are not taken into account when decisions are taken (e.g. causing pollution). Equally, there will be less incentive for individuals or businesses to reduce risks if they will not benefit wholly from risk reduction measures, even if society as a whole would gain; and,
- **public goods**¹. Markets generally do not have appropriate incentives to provide public goods, and it may be appropriate for government to intervene to ensure they are provided (e.g. the protection conferred on all by vaccination; flood defences), where the benefits outweigh the costs.

Other rationales

2.3 In addition to these standard economic rationales, there are other reasons for intervention:

- **existing social and physical contexts** may not be conducive to the avoidance of inappropriate risks - in some cases, unnecessary and unwise risks may even be encouraged (e.g. children daring each other to cross railway lines);
- **past decisions** - our society sometimes faces the unhelpful legacy of past decisions, because of either less concern or less knowledge about risk (e.g. asbestos);
- **inequalities** - there are also inequalities in terms of the degree of risk and the natures of hazards that confront people (e.g. poor local air quality);

¹ Public goods are those that are non-rival and non-excludable when used or consumed. Non-rival means that the consumption of the good by one person does not prevent someone else using or consuming that good. Clean air is a good example. Non-excludable means that if a public good is made available to one consumer it is effectively made available to everyone, and can give rise to a problem called free-riding. This is when some consumers fail to pay for the provision of the public good because they expect others will do so. See Annex I of the Green Book, <http://greenbook.treasury.gov.uk/annex01.htm>

- **involuntary exposure** to risks – some can be exposed to risks which they can do little to mitigate or prevent themselves (e.g. exposure to natural radon emissions); and,
- **benefits can bring risks and uncertainties** – for instance with new technology, new risks or uncertainties will need to be compared to the benefits that might come, and government may have an important role to play in determining whether the risk is acceptable compared with the benefits.

2.4 Therefore, government has a role to protect the public and improve public health, as an employer itself, legislator and regulator, and through public spending. The public should also bear responsibility for its own welfare where social institutions (government and commercial) have fulfilled their responsibility for providing sufficient and appropriate regulations, information and resources.

2.5 The principles that should underpin government action in these contexts are as follows²:

1. Interventions should be evidence based, though the lack of conclusive evidence should not, where there is a threat of a serious risk to the public's health or safety, block action proportionate to that risk;
2. Interventions should tackle *as directly as possible* the specific market failures, public concerns and other socio-economic problems identified, and the specific causes and consequences of the hazards and risks;
3. The total costs of an intervention to the government, business and society must be kept to a minimum and be acceptable when compared to benchmarks for what individuals on average are willing to pay to reduce risk;
4. The distributional effects of any programme of intervention should be acceptable (aligned with societal equity objectives);
5. Quantitative techniques (in terms of monetised costs and benefits, and risk scores) should aid and not supplant judgment in this area; and,
6. Communication, public involvement, and risk management should be integrated into the decision making process as early as practicable.

EXPERT ASSESSMENTS OF RISKS

2.6 If government action might be justified, a more detailed expert risk assessment should be carried out. Such an assessment will generally require the exercise of judgement, in structuring the analysis, evaluating relevant data, conducting sensitivity analysis etc., and important assumptions should be explicitly stated. Risk assessment methodologies can be highly specialised and a detailed discussion of techniques is outside the scope of this guidance.³

2.7 Although assessment methods are specific to the nature of the risk being examined, a robust assessment should generally include the following stages:

² Many of the principles described are taken from *Securing Good Health for the Whole Population*, Derek Wanless (February 2004), p165

³ Generic and technical guidance is widely available and includes: DETR, Environment Agency and IEH (2000) Guidelines for Environmental Risk Assessment and Management. London: The Stationary Office. The HSE's approach to risk management can be found at <http://www.hse.gov.uk/risk/index.htm>

- hazard identification – where the hazards being examined are defined;
- risk characterisation – where the potential effects of the hazards are identified;
- risk estimation – where the probability and magnitude of effects are estimated; and,
- risk evaluation – where the importance of the estimated risks is evaluated.

2.8 Risk assessments should also include an analysis of potential uncertainty surrounding the risk estimate, which may be substantial if risks are unpredictable or evidence is weak. Where uncertainty is very high there may be need to consider precautionary action (see paragraph 3.15).

ASSESSING PUBLIC CONCERN

2.9 In addition to the risk assessment, the level of public concern should be assessed at this stage. Public, non-expert or lay perceptions of risk can differ greatly to those of experts because:

- they may have a different understanding of the nature and magnitude of the risk (and may have less information about risk);
- they have different and diverse views about the acceptability of risks, particularly if they are likely to suffer because of them; and,
- experts and the public may define risk differently.

2.10 The public will hold genuine views and concerns about risk, even if they have a non-expert level of technical understanding. Involving lay stakeholders in the decision-making process can assist the creation of policy choices that address these concerns directly, and can greatly improve policy choices and the public's acceptance of them, particularly where they are personally affected. It is therefore appropriate that such concerns are assessed carefully.

2.11 Appendix A discusses how the public's views can be captured, and provides a framework to help test how important the concern is, what is driving it, and how the concerns might be addressed. Six indicators are provided which research suggests correlate well with overall levels of concern⁴:

- **familiarity and experience of the risk** – in general, people are more concerned about risks which are new to them and about which they have only a little knowledge or experience;
- **understanding of the cause-effect mechanism** – people may be more concerned if the cause-effect mechanism is unknown or uncertain (e.g. if experts disagree) or if they themselves find it difficult to understand from the available information what effects hazards may have and how likely it is that they may be harmed;
- **equity of the consequences of the risk and the associated benefits** – people tend to be more concerned if they perceive that the effects fall unfairly on a

⁴ The set of indicators was chosen as being reasonably transparent, representative categories of public concern that the available 'research suggests, would correlate well with any alternative sets that might be used. A background note on developments in this area by Baruch Fischhoff is available. See http://greenbook.treasury.gov.uk/documents/Fischhoff_Background.pdf.

specific group in society, particularly if they themselves are part of that group;

- **fear of the risk consequences⁵** – people are naturally more concerned if the form of harm is particularly horrific, such as if it involves: long term extreme pain; impacts on future generations; widespread impact; or because the harm (or degree of harm) is unknown or uncertain and could be very severe and irreversible. There may well be other reasons why fear is particularly high, which might depend on individuals' perceptions and the context;
- **control of the risk** – people tend to be more concerned if they feel they have no control over the risks involved; and,
- **trust in risk management** – people tend to be more concerned if, not having personal control over the risks involved, they also do not trust those responsible for managing the risk on their behalf.

2.12 These aspects of concern are important to assess, as they will later help direct the policy response and the communication strategy. Some concerns will be valid; others will be unsubstantiated by the scientific, or other, evidence; still others will be generated by uncertainties about which there is little evidence either way. It is important that understanding and (where possible) resolving these different viewpoints should be an explicit objective, which is likely to require involving the public (through 1:1 interviews, focus groups, and potentially through surveys, opinion polls, public forums, etc.). Social researchers and statisticians should be able to advise on the best data collection methods.

MANAGING THE APPRAISAL PROCESS – PUBLIC INVOLVEMENT ---

2.13 Once a risk assessment and an assessment of public concern have been carried out, the extent of problems to be addressed should be clearer. It may then be the right point to consider how to involve stakeholders and the public. This is often a vital part of the decision making process. It is important at an early stage to understand their views and concerns about particular risks, to involve them in the decision making process and later to explain how their views have been taken into account, and to provide the reasons for decisions made.

2.14 Where either effects are highly uncertain or probabilities are unknown (or both), traditional cost benefit, cost effectiveness and risk analyses are of less help as they do not provide clear cut rules or methods that can be applied to reach decisions. In such circumstances, it is highly advisable to involve stakeholders in a deliberative process to balance the possibilities for over- and under- protection.

⁵ As discussed more fully in Annex A with reference to research relating to the indicator of 'Dread'.

Box 1 - Involvement**Government will seek wide involvement of those concerned in the decision process**

Government will actively involve significant stakeholders, including members of the public, throughout the risk identification, assessment and management process. This will support timely and targeted action. Two-way communication will be used in all stages of policy development, risk assessment and risk management. Where there are differences in interpretation it will aim to clarify these through open discussion, and it will seek to balance conflicting views in a way that best serves the wider public interest. It will explain how views obtained through consultation have been reflected in its decisions.

(Government's Principles of Managing Risk to the Public, Annex B)

2.15 In addition, there may well be different and conflicting views about the severity and acceptability of a hazard or risk. In such cases, again, the participation of stakeholders in reaching decisions can be important, through citizens' panels and conferences. Ortwin Renn describes a so called risk management 'ladder', by which as the extent of uncertainty, ambiguity and conflicting viewpoints increases, so risk management strategies move from being routine (undertaken by experts, using well established evidence) through to being highly participative (undertaken by all stakeholders, working their way through the uncertainties and their conflicting standpoints).⁶

2.16 Guidance exists on various tools and techniques to involve the public in decision-making⁷ and advice from communications specialists and social researchers should be sought.

Box 2 - Value of open meetings

There is considerable public concern about the perceived health risks from electro-magnetic fields (EMFs) such as exist around overhead electricity power lines. The National Radiological Protection Board (NRPB) is responsible for recommending guidelines for limiting exposure to EMFs. There is a lack of scientific evidence about health effects and a diversity of practices for control of the possible risk in different countries. NRPB organised a public open meeting in Birmingham in 2002 to consider public concerns with a view to providing input to the development of proposals for limiting exposure. The meeting was conducted under an independent chairman (Lord Winston) and attended by stakeholders from a variety of backgrounds. The open discussions were supplemented by a questionnaire survey of participants to establish what they valued about the meeting and its outcomes administered by NRPB's Radiation, Risk and Society Advisory Group. Feedback on the lessons drawn by NRPB was provided to all participants and these have been used in the recommendations on limiting exposures and in reviewing NRPB's procedures.

⁶ See Ortwin Renn, *The Risk Management Ladder*, <http://greenbook.treasury.gov.uk/documents/riskmanagementladder.pdf>

⁷ See <http://www.policyhub.gov.uk/tools/index.asp#publicinvolve>

OPTIONS FOR RISK MANAGEMENT

INTRODUCTION

3.1 The Green Book provides fuller guidance on option appraisal, and the techniques that should be used, in terms of assessing option costs and benefits, both monetary and non-monetary.

3.2 Interventions should tackle as directly as possible the specific market failures, public concerns and other socio-economic problems identified, and the specific causes and consequences of the risk.¹ Consequently, options should be generated that address both the risk itself, as well as the concerns that have been expressed. Options are rarely completely mutually exclusive – Chapter 5 discusses how the best options should be refined into a consistent strategy, which may involve action on a wide range of fronts.

POTENTIAL OPTIONS

3.3 The following options, which are *not necessarily mutually exclusive*, should be considered; the circumstances when they might be appropriate are discussed under each heading.

1. Do minimum

3.4 A hazard may be known and its risk an accepted and acceptable part of life. Public concern might also therefore be low. The minor advantages of a particular action to reduce risk might be outweighed by its costs and disadvantages. Some risks associated with sport might have these attributes. Monitoring may still be required though.

2. Monitor the risks and hazards and risk management actions

3.5 Monitoring might be appropriate if the hazard is new or unknown and its effects unclear although within certain boundaries (such that more limiting precautionary actions would be unjustified). Trigger points for action and targets may need to be set. There may be unintended consequences of risk mitigation actions that should be reviewed. Definitions of success could also be established and reviewed.

3. Develop contingency plans

3.6 By their nature, risks may or may not materialise and their impacts may vary from expectations. Contingency planning can be important to ensure that all (or the most important and representative) eventualities can be adequately addressed.

4. Voluntary action

3.7 Government may wish to encourage, formally or informally, voluntary codes, better private or voluntary sector provision of information, or forms of self-regulation. For example, businesses, charities and sports associations might be requested to

¹ See paragraph 2.5, point 2.

provide better information to members and employees of the risks of certain activities; or to develop their own forms of safety inspection.

5. Conduct research

3.8 If the hazard or level of risk is currently unknown, but potentially high – and especially if public concern is high – then carrying out research into either the nature of the hazard or the level of risk exposure might be an obvious first step. However, it may not be possible to design a research method to determine how best to understand and respond to a given hazard, and decision-makers should be prepared for a significant range of uncertainty in the research results. The research costs would need to be set against the potential benefits of new approaches.

6. Specific hazard and risk reduction measures

3.9 Action may need to be taken either by government expenditure or through regulation, which will involve the management of hazards and risks. This might involve steps to reduce the likelihood or reduce the scale of the consequences. Actions might vary greatly, from discontinuing particular activities (removing or avoiding the hazard) to introducing complex safety mechanisms (reducing risks). They are likely to be highly context specific.

7. Communication

3.10 In most cases this is likely to be an essential policy response, regardless of what other action needs to be taken, not least because:

- as society and its technologies become more complex and the nature of risks more difficult to understand, more time and effort is required to communicate in ways that people can understand, to enable them to make informed choices and to place reasonable trust in those managing risks on their behalf;
- it is wrong to think that the views of the government and public do not change and cannot be influenced for the better by good communication.

3.11 The public rarely has full information about health and safety risks; there is a role for government to provide information so that individuals can take more informed decisions. Ensuring impartial information is provided is an important policy response when, for instance, the expert assessment of risk is low, but public concern remains high, or vice versa.² Asking third parties to assess evidence and provide impartial advice and information can be important particularly when public trust is sought. Where risks are concerned, another important and challenging role in communication is to convey uncertainties about the future, particularly to decision makers. In addressing this matter it is of course important to identify what information the public really needs to make an informed choice and the best means to convey the information.

3.12 A good information set could, for instance, identify missing concepts in the public mind, rectify mistakes, reinforce correct beliefs and de-emphasise peripheral concerns. How this information set is communicated will then need to be considered (e.g. through leaflets, advertising, public meetings etc.), and communications' specialists should be involved.

² E.g. the effects of smoking and alcohol; road safety campaigns.

3.13 There is a danger that if there is too much information about risk people might become either immune to warnings or unduly worried. Consideration will continue to be needed at an agency, departmental and cross-Whitehall level over the way in which information about risks is disseminated.

3.14 Given the importance of good communication about risk, policy makers are encouraged to adopt the tools and techniques of risk communication that already exist. These include³:

- **Communicating Risk, GICS guidance** <http://www.ukresilience.info/risk/> (This tool-kit helps policy-makers and others to plan communication strategies, develop an understanding of risk and improve their knowledge of its likely effects.)
- **Communicating about risks to public health. Pointers to good practice.** http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4006604&chk=f3sSqN

8. Precautionary action

3.15 If, as above, the risks and hazards are currently unknown or the uncertainty about their likelihood and/or consequences is very high, but there is a potential for devastating impact, more limiting action may need to be taken (e.g. reflecting the precautionary principle)⁴. Normally, precautionary approaches should be adopted alongside research and monitoring. Consequently, highly restrictive or expensive precautionary interventions should be reviewed on a regular basis in the light of research findings and new data.

9. Pilot studies

3.16 Sometimes the correct policy response is difficult to gauge, and evaluation evidence of a range of pilot initiatives may be required before launching regional or national programmes.

10. Expenditure and subsidies

3.17 Where externalities exist there may be a case for government intervention. Cleaning up areas that suffer from a long legacy of environmental damage might be one example, if no one responsible for creating the damage can be identified. There may be a case for helping individuals be protected from risk (or compensated, if acceptable) where others benefit.

11. Tax and regulation

3.18 Where negative externalities exist, and where the risk is high and public concern is high, regulation can be introduced to ban or limit certain activities or products,

³ The Cabinet Office provides more general guidance on consultation with public, see <http://www.cabinetoffice.gov.uk/regulation/consultation-guidance/>

⁴ Precautionary principle: The precautionary principle is an approach to risk management that can be applied in circumstances of scientific uncertainty, reflecting a perceived need to take action in the face of a potentially serious risk without waiting for results of scientific research. The 1992 Rio Declaration on Environment and Development says: 'In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.'

reducing risks to acceptable levels. However, regulation can infringe civil liberties, which need to be considered (see paragraphs 3.28 – 3.32 below). Taxes set at the level of the externality (or more severely, to include some punitive element), force individuals to take the wider consequences of their decisions into account, by increasing the price of undertaking activities that generate the externality. Taxation by itself does not prevent people from undertaking the activity. The costs of administration and enforcement also need to be taken into account.⁵

12. International action

3.19 Standards may be set internationally, or international experience and judgements assessed for their applicability to the UK.

13. Education

3.20 Some hazards and risks will be important to educate young people about, particularly where they are at risk themselves and can reduce the risk by their own actions. It may be appropriate therefore to work with schools, young people, teachers and parents to try to reduce risks that young people face.

ADDRESSING PUBLIC CONCERNS

3.21 Once the reasons for public concerns have been identified, it may become clearer how best to address these.

Unfamiliarity with the risk cause

3.22 Once people realise they are exposed then familiarity will, of course, only increase. However, it may be undesirable to allow this to happen naturally. Instead, it may be more appropriate to consider the nature of previous exposure and to supplement this with an indirect raising of awareness, including radio or television broadcasts, leaflets, and briefings for local or national journalists. Campaigns must be targeted towards those at risk if they are to be effective. The needs of hard to reach groups will need to be considered carefully.

Poor understanding or risk mechanisms

3.23 A distinction can be made here between understanding by the public, regulators, and the relevant scientific community. If the experts' understand the risk well then public understanding can be improved through the usual information channels. If the experts do not understand the risks then further research and a more precautionary approach may be needed. The understanding of regulators' and others responsible for managing the risk is important because it can determine the effectiveness of risk management. Understanding can be improved and become more widespread through developing policy statements, providing training, summarizing and disseminating academic research and carrying out further research as appropriate.

Inequitable consequences

3.24 Understanding precisely who is affected and targeting intervention to groups at risk to ensure greater equity is an important redistributive action that government can take.

Fear of Harm

3.25 Where people fear particular risks, such views are generally deeply held and not easily influenced. This will need to be taken into account in cases where the level of fear of harm is at odds with the available evidence about the risk: action may not be necessary to increase controls but it may still be needed to provide reassurance.

⁵ Further information on the setting of taxes and subsidies at levels reflecting externalities are available from www.hm-treasury.gov.uk/media/466CB/adtaxenviron02-332kb.pdf. There are a number of issues to consider, including the costs of administration and enforcement, which are beyond the scope of this paper.

Control over exposure **3.26** People tend to be more concerned about risks over which they have little personal control or where they feel their views have not been taken into account. Allowing people to self-regulate, to give informed consent for exposure to the risk, and, where appropriate, ensuring that regulatory authorities are given adequate resources and powers are potential policy responses.

Trust in risk management **3.27** People are often more concerned about risks if they don't trust the sources of information about them. Concern can also arise if the institutions responsible for risk management or regulation are distrusted. People may be concerned about a risk because of the institution's general reputation, even if there is no evidence that the risk in question has been mismanaged or poorly regulated. Trust only develops over time, and can quickly be lost. Public bodies need to: demonstrate good records in risk management; show that they do not have vested interests; consult and respond to concerns; and take precautionary actions where appropriate (see above). Regulators need to show that they have not been captured by any vested interests and are able to take decisive and strong action if necessary. Trusted third parties may be best placed to provide impartial information and under certain circumstances to adjudicate between competing views. Finally, it is important to communicate the extent to which the public can realistically expect to be protected – things can still go wrong even when risks are well managed.

LIMITS TO GOVERNMENT INTERVENTION

3.28 Policy makers should also be aware of the limits to government intervention.⁶ Interventions to reduce risk have the potential to significantly reduce personal freedoms. This is most clear when government acts explicitly to prevent or restrict individuals from behaving in certain ways, or from consuming particular goods. Of course the impact will not inevitably be restrictive – providing people with information that they can use to protect themselves can increase personal freedom.

3.29 In general, if the freedom to be curtailed or limited is a significant one and valued highly by the individual, the state would need strong reasons to impose its will over the individual on public health or safety grounds. Usually, there should at least be a strong consensus that the measure is necessary to prevent harm to others. Government can of course legitimately intervene when one person's freedom to act would infringe others' human rights – for example, a person with a highly infectious disease may need to be quarantined without consent. In other cases, however, the mere fact of social or professional consensus may not provide sufficient justification for action.

3.30 Ideally, individual consent provides the strongest foundation for government action. However, in cases where it is only the individual's health and safety that is at issue, the question of intervention without consent poses challenges. Nevertheless, there are examples where such measures have been enacted and have become accepted. First, individuals may already prefer not to be free to choose, and may accept restrictions (the banning of class A drugs, for example). Second, they may come to accept the reasons behind the restrictions and no longer see them as an imposition (legislation to require people to wear front seat safety belts, for instance). However, it is important to recognise that measures should be justifiable in the public interest and to individuals as a reasonable restriction of their freedom.

⁶ The paragraphs in this section are adapted from *Securing Good Health for the Whole Population*, Derek Wanless (February 2004).

3.31 Where evidence on what works is uncertain or non-existent, measures should be introduced on a pilot basis first and fully evaluated before being extended. Pilot studies can be used to test not just the evidence of what works and what does not, but also the acceptability and enforceability of a particular public health and safety measure. In some cases, health and safety measures may have to be introduced first before the full benefits to the public are realised, allowing public opinion to become favourable, (again as with requiring people to wear front seat safety belts). Review points should be built in to test expectations of growing consensus. However, such a change can never be guaranteed, and decisions should be reviewed to ensure that a reasonable consensus has developed. Measures may need to be modified or withdrawn as a consequence, and ministers and officials should be prepared to accept this as part of the policy development process.

3.32 Finally, decisions may be devolved. Devolved and regional assemblies and local authorities may be better placed to judge whether a particular measure is important and enforceable, and how to introduce it successfully.

Box 3 Assessing public concerns on a continuing basis

The National Radiological Protection Board (NRPB) provides scientific advice on ionising and non-ionising radiation. The scientific advice, in the form of exposure standards or guidelines, forms the basis of regulatory policies for ensuring that people are adequately protected. Radiation risks have the potential to mobilise public concerns, for example about overhead electricity power lines or mobile phone masts. NRPB has a substantial public information programme and provides a public information service on radiation risks. It uses data from public enquiries to identify common misperceptions or particular concerns that need to be addressed in communication strategies. It responds publicly to media reports to correct misinformation. NRPB is advised by a Radiation, Risk and Society Advisory Group (RRSAG) chaired by a former Chief Medical Officer and with diverse membership including a head teacher, science media communicator, environmental lawyer, psychologist and risk specialists from non-radiation disciplines. RRSAG assists in evaluating the effectiveness of NRPB's communication activities and identifying areas for attention. For instance, it has supported an investigation into the understanding of and attitudes to risk among school children.

APPRAISING COSTS AND BENEFITS

A - INTRODUCTION AND DISCUSSION

4.1 Once a range of options has been created, they should be assessed by estimating their costs and benefits, and/or by their cost effectiveness.

Assessing costs

4.2 The Green Book provides more guidance on how proposals should be costed¹ and there is no need to duplicate the guidance contained there. In essence, the full economic costs should be calculated and adjustments made for risk and optimism bias². Questions of affordability and viability should also be addressed in the appraisal.³

Comparison with benefits

4.3 Cost benefit analysis (CBA) can provide an assessment of how much society wants to devote to reducing the risk of fatalities and other harms, given its limited resources and competing demands; and both CBA and cost effectiveness analysis (CEA) can help determine where and how best to deploy the resources available for reducing risk and preventing harm.

4.4 In these respects, CBA and CEA are important tools in the decision-making process. However, neither approach is perfect, for a variety of theoretical, technical and practical reasons, so particular methods will tend to suit certain contexts. They may also produce different results. This means that policy makers and specialists should be aware of the differences, advantages and disadvantages of each. The two are described below and compared in more detail in Annex C.

Cost benefit analysis and the valuation of preventing a fatality

4.5 Cost benefit analysis quantifies in monetary terms as many of the costs and benefits of a proposal as feasible, including items for which the market does not provide a satisfactory measure of economic value.

4.6 Where benefits might also bring the risk of death and harm, or if the benefit itself is the reduction of death and harm, CBA becomes complicated. A basic principle in CBA is that benefits should be valued in monetary terms wherever feasible, so that such comparisons can be made using a common unit of measurement - money. However, preventing death ultimately has no monetary value – obviously, not least, to each individual concerned, and even the attempt to quantify it may be seen by some as unwelcome. There is therefore a paradox⁴; while society generally recognizes that each individual life has an intrinsic and absolute worth, it chooses neither to spend all its resources nor to regulate only in order to prolong life and prevent the risk of death. The

¹ See <http://greenbook.treasury.gov.uk/chapter05.htm#valuing>

² See <http://greenbook.treasury.gov.uk/chapter05.htm#adjusting>

³ See <http://greenbook.treasury.gov.uk/chapter06.htm>

⁴ Broome (1999) discusses the paradox in Chapter 11, 'Trying to Value life', in *Ethics out of Economics*.

question is how much is it reasonable to spend and regulate in this area and how to compare this activity to other costs and benefits.

WTP and WTA 4.7 In the absence of a market, various techniques can be used to calculate economic values. These include analyses of people's actual behaviour, as well as surveys⁵ of people's 'willingness to pay' (wtp) for a particular measure (e.g. to reduce risk), or how much, by way of compensation, they would be 'willing to accept' (wta) for them (e.g. a greater exposure to risk).⁶ Economists have attempted to identify the value of preventing fatality through such wtp surveys. Survey questions involve typically:

- contingent valuations (CV): for instance, respondents have been asked to consider how much they would pay for a safety feature that would reduce their annual risk of fatality from, for example, 8 in 100,000 to 4 in 100,000, concentrating on their own risk and assuming that others' safety would be unaffected; and,
- standard gambles (SG): for instance, respondents have been asked to indicate the probabilities they would find acceptable if they had to choose between a treatment following a road accident with an imperfect but certain outcome, and one that is uncertain, either bringing the respondent back to normal health or causing death.

4.8 From responses to such questions, the implied valuation that people put on preventing fatality can be calculated. In the absence of an alternative method, and faced with the paradox described above, these substantial exercises in valuation remain the best attempts to provide an understanding of how much it may be worth spending and regulating to prevent fatalities.

Cost effectiveness and cost utility analyses

4.9 Cost effectiveness analysis compares the costs of alternative ways of producing the same or similar outputs. One relevant form of CEA uses the 'quality adjusted life year' (QALY)⁷ output measure, which is described below.

QALYs 4.10 QALYs are estimated by assigning every life-year a weight on a scale where 1 represents full health and zero represents death⁸. The most common methods of determining the health related utility values to weight QALYs are:

- the standard gamble (see above also): an individual is asked to consider two alternatives: full health with a risk of death and an imperfect state of health with no risk of death;

⁵ See DTLR and DEFRA - Economic Valuation With Stated Preference Techniques, November 1, 2002.

⁶ In practice, most surveys have been conducted using a willingness to pay rather than a willingness to accept approach. 'Willingness to accept' values tend to be higher than those from willingness to pay – people have a natural reluctance to part with what they already have, often because there are no obvious substitutes. Other hypotheses put forward to explain the difference include: *prospect theory* (people value the same absolute loss more highly than the same absolute gain, viewed from the same starting point e.g. the gain in safety from a risk reduction of 1 in 100,000 may be valued at £x by an individual while that same individual would value a loss in safety from a risk increase of 1 in 100,000 as £2x); *uncertainty* (people are more cautious in the face of losses and therefore place a higher value on them); and *protest* (people refuse or find implausible the property rights implied by the WTA format). This is reflected in higher values required for compensation for loss than in purchase values of the same things. Health is an obvious example. For a fuller discussion, see Hanemann (1991) and Kahneman, Daniel, Knetsch and Thaler (1991). For the class of public goods that require annual payments or their equivalents to maintain a given level of the good (e.g. air quality, transport, safety, food safety, water quality etc.) it has been shown that the willingness-to-pay framework is the most appropriate. Mitchell and Carson (1989)

⁷ Usually referred to as the cost-utility analysis. Cost-effectiveness analysis refers to any analysis of costs for which outputs can be expressed in unit (though not monetary) terms., e.g. the numbers of lives saved. Using qalys is referred to as cost utility analysis because they attempt to measure aspects of 'utility' or 'happiness'.

⁸ There are some health states so severe that respondents in surveys class them as worse than death.

- the time trade off: an individual is asked to consider how many years in full health would be equivalent to, say, five years in a given health state;
- the visual analogue scale: a thermometer type scale where full health is shown at the highest point, and worst possible health state is shown at the lowest point. Individuals simply indicate where on the scale they feel that the health state is located; and,
- the person trade-off: individuals are asked what number of people being cured from one particular state is equal to, say, ten people being saved from death.

4.11 Predefined sets of utility weights, derived using some of the above methods in large surveys of the general population, are also available. These can be applied to health states that have been described using generic health-related quality of life questionnaires. The 'EQ-5D' scale is commonly used.

Box 4: QALYs – the EQ-5D scale (European Quality of life – 5 dimensional scale)⁹

Scores for the EQ-5D are given across 5 different dimensions: mobility; pain/discomfort; self-care; anxiety/depression; and the ability to carry out usual activities such as work, study, housework, and leisure pursuits). Each of these is scored out of 3 (e.g. for mobility – no problems; some problems walking about; confined to bed), giving a total possible combination of 243 health states (in addition, unconsciousness and death are included). Using the techniques above, patients are asked to self-score their health state and their views about their state of health relative to normal health (a score of 1) and death (a score of 0). Some examples of the health states (and their QALY values in brackets) are as follows:

- 11111 – no problems (QALY in such a state: value = 1.0)
- 11221 – no problems walking about; no problems with self-care; some problems with performing usual activities; moderate pain or discomfort; moderately anxious or depressed (0.760)
- 12321 – no problems walking about; some problems washing or dressing self; unable to perform usual activities; some pain or discomfort; not anxious or depressed (0.516)

Scoring procedures such as this should be used with great care. Further information about the EQ-5D scale and how to contribute and gain access to detailed research findings is available at <http://www.euroqol.org/web/>

⁹ A useful short guide to QALYs is 'What is a QALY?' by Philipps and Thomson, available at www.evidenced-based-medicine.co.uk

B – RECOMMENDED APPROACHES

Introduction

4.12 The previous section described the two main approaches to the economic analysis of risk that are current. This section provides some recommendations on how these approaches should be adopted in practice. Annex C compares the two approaches in more detail.

1. Assumptions should be explicitly stated

4.13 Implicit in the two main recommended approaches are the following assumptions:

- using ‘willingness to pay’ benchmarks incorporates the assumption that everyone at risk from accidental death should be treated as if they were of average income and wealth, producing average net output, of average age and expressing an average level of risk aversion;
- when using the ‘willingness to pay’ framework the aim is to maximise welfare and it is assumed that individual utilities can be added together to generate societal utility; and,
- using QALYs as an output measurement also incorporates these first two assumptions - and also assumes that the appropriate objective is to maximise quality adjusted life expectancy, and that all QALYs should be treated equally, irrespective of the person and type of ill-health at stake.

4.14 These are important assumptions to be explicit about, as others may make alternative assumptions that would give rise to different conclusions.

2. The reason for the choice of cost benefit or cost effectiveness analysis should be made explicit

4.15 In general, cost benefit analysis is preferred to cost effectiveness analysis as it allows direct comparison between benefits and costs, but there are advantages and disadvantages with both approaches discussed in Annex C which mean that both could be used in the decision making process. In particular, the disadvantages of each method need to be explicitly addressed. In certain cases, disadvantages of specific techniques can be overcome through more sophisticated analysis, and indeed the approach to economic analysis in this field is a developing area.

4.16 In certain cases, a cost effectiveness analysis will be all that is required and would yield the same results as a cost benefit analysis, which might be more time consuming to complete. In most analyses, the focus should be to support the decision-making process.

4.17 In many cases, CBA and CEA will produce similar rankings of options. However, it can be important to value benefits if:

- alternative and mutually exclusive courses of action are very different – in which case monetary values may represent the best measure for comparison;
- it is not known or agreed that the benefits are worth the cost;

- an appropriate budget limit to achieve the benefits is not known and needs to be set;
- externalities are material to the decision (for instance, if the cost of negative externalities is to be reflected in taxation) and are therefore necessary to value; and,
- in cost effectiveness analysis, more than one outcome or output measure is relevant (and therefore the proportion of benefit between them is unknown, and hence the relative advantage of a particular option.) Even so, CBA may not be the appropriate approach to use in such circumstances. Multi-criteria analysis may be more acceptable, by which weights are put on the different outcomes, and different options scored.¹⁰

3. Appropriate willingness to pay values should be used as benchmarks

4.18 In cost benefit analysis the most appropriate willingness to pay values should only be used as benchmarks, and, where appropriate, researched.

4.19 For example, one benchmark in use is derived from research for DfT, which suggests a valuation range for preventing an accidental fatality (VPF) of £1 – 1.5 million¹¹ (in 2002 prices). This range has also been reviewed in the contexts of rail transport, domestic fires and public fires. Similar values were elicited in these alternative scenarios; it may therefore be appropriate to consider this range in the context of similar scenarios involving accidental and near immediate loss of life. It would not however be appropriate to use this range for a specific, known individual.

Box 4: Example

Suppose government is considering introducing a particular safety measure, as a result of which it is expected that 25 fewer people will die in traffic accidents in a given period.

A benchmark range for an acceptable cost over the same period is £25 – 38 million (2002 prices).

Other considerations would apply, for instance, if a greater proportion of the affected were likely to be children, or if there were a high level of public concern.

4.20 Other values for injuries have been developed in the specific context of roads as table 2 shows.

¹⁰ See http://www.odpm.gov.uk/stellent/groups/odpm_about/documents/page/odpm_about_608524.hcsp

¹¹ It is based on a well-established 'value of a statistical life' (VOSL) used by the Department for Transport, £1.25 million, based on 2002 road traffic data. This value has been used by the Home Office, HSE, Environment Agency, Food Standards Agency and other government bodies. See Annex C for the detailed breakdown of this VPF into its constituent parts. It is important to note that this is not an insurance-based value. The values in this guidance should not in any way be used for insurance or for compensation claims. For the specific road safety values, and how to up-rate them, see the Department for Transport's Highways Economics Note 1 (HEN1), 2002 at http://www.dft.gov.uk/stellent/groups/dft_rdsafety/documents/page/dft_rdsafety_026183.hcsp. See also paragraphs 5.45 - 5.47 in the Green Book, <http://greenbook.treasury.gov.uk/chapter05.htm#adjustments> which discusses the up-rating of values in appraisal more generally. The calculation for up-rating any value in line with GDP is provided, along with the relevant annual data, at http://www.hm-treasury.gov.uk/economic_data_and_tools/gdp_deflators/data_gdp_index.cfm. Research in 1997 concluded that an acceptable range was £0.75 – 1.25 million, or +/- 25% of the central value £1 million.. Beattie et al (2001)

Table 1

Injury Severity	Lost output (gross)	Medical and ambulance	Human costs	Total
Serious	16,540	10,030	113,870	£140,450
Slight	1,750	740	8,340	£10,830

Source: *Highways Economics Note No.1, 2002*¹²

4.2.1 It would be appropriate to carry out bespoke studies to elicit values for other specific contexts, or to use the results of other WTP studies, in the following circumstances:

- where the cost of research is likely to be proportionate to the scale of the benefits that may be achievable;
- where it is likely to improve the evidence base, and hence the decisions to be taken. For instance, if the context is markedly different from other situations that have already been analysed; and
- where the results of the research could be used in other circumstances, which collectively would justify the research expense.

4. Valuations should be averaged across society

4.2.2 For straightforward equity reasons, differences in wealth should be ignored when establishing benchmark values. Consequently, this means that national average valuations of preventing fatalities and other harms should be used. Where target groups are poorer than the national average, national average valuations should still be used.

4.2.3 No distributional adjustment should be made on the basis of income; clearly, while an additional amount of money is of greater value to the less affluent than to the affluent, the assumption in this guidance is that life is of the same intrinsic worth to all. However, the less affluent may be less able to protect themselves against certain risks, and this should be taken into account when developing policy responses.

5. High-risk levels should be assessed for tolerability and acceptability

4.2.4 Willingness to pay values for reductions in risk tend to increase with the level of initial risk.¹³ If there is a high risk of serious harm, then clearly there is a greater duty to ensure that the risk is reduced (or the hazard rendered less harmful), where that is possible. This is assessed using the concept of the ‘tolerability of risk’.¹⁴ In essence, high risks should be avoided, prevented or reduced virtually whatever the cost implications; very low risks should be mitigated further if the costs are justified¹⁵; and in the intermediate range, risks should be reduced ‘as low as reasonably practicable’. See Box 5 for an interpretation of this guidance.

¹² Available at: http://www.dft.gov.uk/stellent/groups/dft_rdsafety/documents/page/dft_rdsafety_026183.hcsp. HEN I 2002 provides more detailed information on the use of values in the context of road safety appraisals.

¹³ see Appendix C.

¹⁴ Described in Reducing Risks Protecting People, HSE 2001.

¹⁵ Even if there were a very low risk of fatality; for instance, lives could still be saved by simple, inexpensive measures that would be worthwhile if the number of fatalities were reduced.

Box 5: Tolerability of risk and ‘as low as reasonably practicable’ (ALARP)

The legal definition of ‘as low as reasonably practicable’ (ALARP) was set out by the Court of Appeal in *Edwards v. National Coal Board* (1949): “ ‘Reasonably practicable’ is a narrower term than ‘physically possible’ ... a computation must be made by the owner in which the quantum of risk is placed on one scale and the sacrifice involved in the measures necessary for averting the risk (whether in money, time or trouble) is placed on the other, and that, if it be shown that there is a gross disproportion between them – the risk being insignificant in relation to the sacrifice – the defendants discharge the onus on them.”

The practicable application of this is to ensure that the exposure of workers and the general public to risk is ‘as low as reasonably practicable’. One framework (below) has been devised to interpret this requirement¹⁶.

Category	Action required	Criteria
Intolerable	Extremely reluctant to accept any arguments for not doing more to reduce the risk	If for workers, a risk of death of 1 in 1,000 per annum. If, for the general public, it is a risk of 1 in 10,000 per annum.
Tolerable if as low as reasonably practicable	A case specific ‘ALARP’ demonstration is required. The extent of demonstration should be proportionate to the level of risk.	Risk levels broadly between ‘intolerable’ and ‘broadly acceptable’.
Broadly acceptable	No case specific demonstration is required. The ‘ALARP’ demonstration should be fairly straightforward, assuming existing codes of practice etc. are up to date.	For workers and the general public, if it is a risk of death of 1 in 1,000,000 per annum.

4.25 Clearly, some health risks will be very high for individuals or particular groups at risk. The underlying risks, such as a genetic predisposition to certain illnesses, may not yet be easily reduced, merely treatable if the medical condition emerges. Here the test of ‘reasonably practicable’ may be generally more appropriate with the concept of ‘tolerability’ being less relevant.

6. Adjustments to the benchmark willingness to pay value should not be made for old age alone

4.26 Adjustments to the benchmark willingness to pay value above should not be made for old age alone.

4.27 However, where competing risks and/or co-morbidities¹⁷ exist – the likelihood of which increases with age - it may be reasonable to use different willingness to pay benchmarks (see ‘current and recent research’ in Annex C) and inappropriate to use the valuation for an accidental death of £1 – 1.5 million. For instance, where death would in

¹⁶ For practical guidance on applying this and other risk management frameworks, see <http://www.hse.gov.uk/risk/theory/r2p2.htm>

¹⁷ Co-morbidity is the presence of one or more diseases in the same individual. Competing risks exist when two or more risks affect the same individual.

any case be imminent as a result of the presence of other diseases or risks over which there is little or no control, clearly the benefit of reducing the particular risk in question would be of much less value. However, in such cases, it may also therefore be consequently more appropriate to ensure that the morbidity present is reduced. In other words, if life cannot be extended at an appropriate cost, improving the quality of life may become of greater importance, and the QALY approach will be a more appropriate one to use.

4.28 In cost effectiveness analysis, using QALYs, there is a risk that older people may be discriminated against. In developing policy, the underlying assumptions of the analysis should be reviewed to ensure that this particular disadvantage is acceptable. For instance, the imputed value of a QALY of an older person to provide parity with a younger person could be calculated and then assessed for reasonableness.

7. Children may require higher levels of intervention

4.29 While there is insufficient evidence to support a particular adjustment in the cost benefit analysis, the state may be prepared to spend or regulate more to prevent harm to children, not least for the following reasons:

- parents may be more conservative in their decisions to expose their children to risks than they are themselves;
- children have less ability to take voluntary and rational decisions about risks, potentially justifying higher levels of intervention; and,
- risks to children may be less certain in their impact and a more precautionary approach could be justified.

8. Mortality and morbidity tradeoffs should be made explicit

4.30 It is important to show scenarios and to use sensitivity analysis to demonstrate different choices available to decision makers, for instance, that might show how government resources could be allocated to achieve significant reductions in morbidity against only small reductions in the number of prevented fatalities.

4.31 Nevertheless, it is hard ethically to trade-off lives saved with improvements in the quality of life. Where emergency cases arise for instance, this problem becomes immediately apparent. In practice, in the NHS, for emergency cases, all patients are treated as a matter of course before considering whether further treatment of any underlying chronic medical condition is justified. As mentioned in Chapter 1, the guidance is not designed to help in deciding the appropriate intervention for a specific, known individual, but to help develop policy responses where whole groups or populations are at risk.

Box 6: Example – A simple approach to QALYs

A safety measure could be introduced that would involve preventing approximately 100 people per year from suffering an average loss of 5 QALYs each, due to chronic health effects. As a result it is estimated that:

$$\begin{aligned}\text{Expected QALYs gained} &= 100 \times 5 \\ &= 500\end{aligned}$$

Using current benchmarks for QALYs¹⁸, an acceptable maximum cost of preventing this loss is: $500 \times \text{£}30,000 = \text{£}1.5 \text{ million}$. Alternatively, this resource might be spent to prevent a single expected fatality per year, as it is close to the upper benchmark.¹⁹

9. Uncertainties should be reflected in the analysis and in its presentation

4.32 There are often uncertainties over the accuracy of the results of technical analyses because of various difficulties in assessing risks and hazards. The underlying risks and the nature of the hazard are often unknown, even to experts, and often there can be poor understanding of the relationships between cause and effect. In many cases, the expert assessment of risk will require a number of assumptions to be made, not least with regard to the impact of the policy options under consideration.

4.33 As a result of these uncertainties, scenario and sensitivity analysis should always be used. In essence these techniques test the robustness of the conclusions drawn by changing the assumptions and estimates of key variables that have been used. Expert help is often required to perform the required modelling work and care should be taken to involve a wide enough range of inputs to ensure representation of a comprehensive set of scenarios.²⁰

4.34 The range of results should be used in presentations to decision makers, perhaps in the form of a range of figures or in presenting best, worst and expected case scenarios, and the lack of certainty and important assumptions should be brought to their attention.

10. Reasons should be given for stricter regulation than usual or expenditure higher than the CBA benchmarks

4.35 As well as the CBA or CEA, non-monetary issues should be considered. Reasons for stricter regulation than usual, or expenditure than is higher than the benchmarks in the CBA, should be given and made publicly available. Among the legitimate reasons for such action may be:

- to regain public trust (which might be indicated by the assessment of public concern);

¹⁸ See Annex C

¹⁹ See also the value of a qaly, Annex C

²⁰ Risk simulation using a technique called 'Monte Carlo' analysis is explained further in the Green Book. See Annex 4, paragraph 28, p.87 <http://greenbook.treasury.gov.uk/annex04.htm#monte>

- commercial judgment (e.g. if consumer confidence might be significantly threatened, stricter controls may well be acceptable); and
- precautionary action; and
- emerging evidence suggests that individuals are willing to spend more to avoid particularly feared forms of death (such as cancer-related fatalities) ²¹.

4.36 One question raised is whether issues of concern (such as those in Annex A) can justify higher expenditure.

4.37 Policy makers should still consider whether there are ways of achieving the same outcome but at a lower cost – reflecting the principle that costs should be minimised. For instances, issues of concern may be addressed by greater public involvement in the decision making process and better communication. However, there may be circumstances in which the public will only be reassured when action is taken which would imply very high levels of expenditure to prevent fatalities and other harm. In such cases, it may be appropriate to ask the public (using the techniques described) whether such expenditure is justified, and perhaps provide alternative scenarios of public expenditure (or perhaps risks that have not currently been tackled so well). Finally, if the public's concern remains and the public appears to accept the higher cost implications, this may be a legitimate reason for making the case for higher expenditure. Such decisions should be reviewed periodically, as public opinion can change over time.

4.38 Finally, it is important to recognise that while all have the same rights to raise their concerns, the extent to which those concerns are valid should primarily be considered by those who have the knowledge, skills and experience to measure or estimate the strength of relationships between cause and effect, the probability of harm occurring, and the range of uncertainty, by their systematic observation, empirical data collection or rigorous modelling.

Non-monetary considerations

4.39 CBA and CEA are tools to help decision makers. However, there may well be advantages and disadvantages that cannot be expressed in monetary terms (CBA) or even in unit terms (CEA). If they are important to consider, they should still be clearly described. Such advantages and disadvantages may well be crucial to the decision in an appraisal.²²

²¹A multiple that could be applied to the VPF of £1-1.5 million should be provided from research for the HSE in the autumn 2005. Until then the 'switching' value of the multiple should be calculated and assessed for reasonableness. The switching value is the point at which a decision would change, e.g. from a proposition considered good to poor value for money. (The HSE currently uses a multiple of 2.)

²² See <http://greenbook.treasury.gov.uk/chapter05.htm#considering>

DEVELOPING AND EVALUATING IMPLEMENTATION STRATEGIES

DEVELOPING OPTIONS INTO SOLUTIONS

5.1 The work recommended hitherto amounts to, inter alia: analysis of the rationale for government action, which can help direct the policy response; risk assessment; consideration of public concern; the generation and appraisal of options for intervention, including the development of appropriate communications. This work, however, must be planned and executed in an integrated, coherent way, as far as achievable within the time constraints that policy makers often experience. It is worth repeating the Green Book guidance that all options should be revisited, as they will rarely be mutually exclusive.

5.2 The final part of the decision making process is to bring all the options together into a coherent strategy for implementation. This guidance recommends that the decision-making process is made publicly available before the event, and that, at the very least, the basis of decisions is explained to the public when they are made.

Implementing policy

5.3 Guidance on project and programme management is available elsewhere and is not worth repeating here although much of the generic advice available will be relevant to developing programmes of action¹. However, the specifics of managing public health and safety risks will involve in particular:

- the need for clear communication strategies;
- monitoring of costs, risks and hazards, particularly where highly interventionist action has taken place, or where the evidence base is weak; and
- continuing to listen to minority positions and being open to the possibility of adapting or changing responses in the light of new evidence.

EVALUATION

5.4 The evaluation of expenditure or regulation should be undertaken to assure decision makers and the public that measures introduced to reduce risk and concern have been effective². The data required for evaluation should be considered, and arrangements for establishing suitable monitoring systems prepared from the outset. Questions that should form part of the evaluation might include:

- How has the risk and hazard been reduced? How many actual fatalities, serious and slight injuries have been recorded? How does this compare to the predictions made in the appraisal?

¹ From April 2005 onwards, OGC will lead in taking forward the recommendations from the Office of Public Sector Reform (OPSR) initiative Improving Programme and Project Delivery (IPPD) designed to improve programme and project management in departments. To help departments adopt better practices, OGC, in partnership with the Centre for Management and Policy Studies (CMPS), is up-dating the top management master-classes supporting the Senior Responsible Owner role. The OGC is also developing new training for the Investment Decision Maker role.

² See also chapter 7 of the Green Book, <http://greenbook.treasury.gov.uk/chapter07.htm>

- Are the reasons for intervention still valid?
- Is the scope of the risk and hazard the same?
- Has the risk profile changed?
- Is there evidence of cause and effect – have the changes in risk occurred due to the policy response?
- What is the level of public concern? Has this changed?
- Have there been any unanticipated effects – negative or positive?
- What were the actual costs, direct and indirect?
- How might intervention be improved?
- What transferable lessons can be identified for other existing or planned policies?
- To what extent can we assign effects to the intervention, or to other factors?

5.5 Ensuring that the right evaluation questions are asked and can be answered is particularly relevant when designing pilot studies, as the results from these will inform regional and national schemes.

5.6 Where imputed values are very high, the reasons should be evaluated ex post, (and explicitly justified when appraised ex ante). Overly high values could imply that resources are being directed at health and risk when they could be used to better effect elsewhere in the economy.

5.7 The ex post evaluation of decisions can impute values for preventing fatalities, and other values, which are much higher than could be justified at the time of the evaluation. However, analysts should avoid jumping to the conclusion that therefore a poor value for money decision has necessarily been taken. The imputed value may be higher than the benchmarks available because of other reasons. For instance:

- decisions could have been taken when the level of risk was unknown and which has subsequently turned out to be lower than expected (i.e., a precautionary approach was adopted initially, but the risk turned out to be much smaller than feared). The recommended approach in situations where expensive precautionary actions have been taken is to monitor continually the situation and to build in specific review points, being prepared to act quickly on the basis of better information.
- other factors might have been taken into account when the decisions were taken, such as business risks (the effect of people not buying products and services because of fear about poor health and safety may well be in excess of the standard ‘values’ generated by willingness to pay surveys). Hence, it would be incorrect to use only the number of prevented fatalities as the unit of analysis, without disaggregating any other benefits. Also, interventions can have multiple impacts, which would also need to be distinguished.

5.8 Finally, some actions may not easily be evaluated, such as certain precautionary approaches. Not being able to develop success measures though is an insufficient reason for inaction.

CONCERN ASSESSMENT TOOL

A.1 This Appendix sets out a framework for understanding people's concerns in order that they can be considered in policy development and in the development of related consultation arrangements and communication strategies. A good understanding of relevant concerns is necessary for developing an effective risk management strategy although the effort expended should be proportionate to the risk in question. The information gained on relevant concerns should inform and assist the development and selection of policy options and the development of the associated communications strategy. For example, a public information programme can be implemented if it is discovered that public concern stems from a lack of understanding about the risk. Being responsive to public concerns and involving the public in decision-making, helps to improve the accountability and transparency of risk management.

UNDERSTANDING THE FRAMEWORK

A.2 The framework is based on the psychometric model of risk perception developed by Fischhoff, Slovic and others, in which characteristics of a risk are correlated with its acceptance. For example, risks that are undertaken voluntarily are generally considered more acceptable than risks that are imposed without consent. Similarly, risks that cause dreaded forms of harm are also considered to be less acceptable.

A.3 The assessment framework is based around six risk characteristics that research suggests are indicators of public concern. These six indicators were chosen as being reasonably transparent, representative indicators of public concern which, from the available research would correlate well with almost any other set that is likely to be proposed.¹

A.4 Two of the characteristics relate to the nature of the hazard (Familiarity and Experience; and Understanding), two relate to the risk's consequences (Fear or Dread; and Equity and Benefits) and two relate to risk management (Control and Trust). Research indicates that each characteristic is correlated with concern so, for example, risks that are perceived to be highly uncontrollable would be expected to associate with a high level of concern. By collecting evidence about these indicators, the framework can help understand the likely nature and strength of concern and its drivers.

Collecting evidence

A.5 Existing public perceptions of risk should be assessed as objectively as possible before policy solutions and communication strategies are designed. This requires an approach that is as open as possible in the early stages of engagement, to enable the public to express what they truly understand, and how and why they feel about a particular risk or set of risks. It is important in carrying out the communication that it addresses all relevant parts of the public to ensure that a representative cross section are reached.

A.6 Even 'risk' itself is a term, which may have different interpretations. For instance, "for some experts 'risk' equals expected loss of life expectancy; for others it is expected probability of premature fatality; for still others, it is total numbers of deaths

¹ A background note by Baruch Fischhoff can be found at http://greenbook.treasury.gov.uk/documents/Fischhoff_Background.pdf

or deaths per person exposed or per hour of exposure”². Given this variety of meanings amongst experts, it is unlikely that the public will have a common understanding of apparently simple terms like ‘risk’, or the precise meaning behind questions about risk.³

Understanding the causes of concern

A.7 Each indicator should be scored on a 5-point scale by reviewing relevant evidence obtained from interviews, focus groups, review of media material, etc. For example, two elements to score the first indicator (Familiarity and Experience) are:

- How familiar are people with the hazard?
- What is the extent of their experience?

A.8 For each piece of evidence a number of bulleted questions act as prompts to explore related issues. For example, the first element under ‘familiarity and experience’ (‘how familiar are people of the hazard?’) has three further prompt questions:

- How familiar is the public with the hazard?
- Are all sections of society familiar, or is familiarity confined to specific groups?
- Are those exposed to risk familiar with it?

A.9 These prompts are intended to give an indication of the range of issues that should be explored to collect enough relevant evidence to come to a decision on the extent of concern and not as literal questions to be asked (e.g. as a questionnaire). They are indicative and not prescriptive or exhaustive lists.

A.10 Having reviewed these prompt questions, a summary of the evidence should be entered in the scoring table.

Scoring indicators

A.11 Once all the evidence has been collected, it should be considered as a whole to score the indicator on a 5-point scale, where Level 1 is associated with the lowest level of concern and Level 5 with the highest. The specific score should be taken as indicative rather than a determinant of a particular action and may be useful in identifying those risks requiring further consideration for action. It may also provide useful information for further evaluation.

Identifying policy responses

A.12 Possible policy responses to each indicator should be entered into the scoring table. Suggested policy responses are discussed in Chapter 4, paragraphs 4.16 – 4.22. **It is intended that the information on concerns should be used to inform but not**

² Page 1110 of Fischhoff, Bostram, Quadrel, - Risk perception and communication, in Detel, R McEwan, J, Reaglehole, R and Tanaka, H (2002), Oxford textbook of public health

³ For instance, in the US, a National Centre for Health Statistics survey question asked: “How likely to you think it is that a person will get the AIDS virus from sharing plates, forks, or glasses with someone who had AIDS?” Fischhoff (1989) asked a relatively homogenous group of subjects to answer this question, and then to say what they thought was meant by considering the amount and kind of sharing that it implied.... These subjects generally agreed about the kind of sharing (82 per cent interpreted it as sharing during a single meal), but not about the frequency (a single occasion, 39 per cent; several occasions 20 per cent, routinely 28 per cent, uncertain 12 per cent). Similar uncertainties about their response levels (e.g. very likely, unlikely, and so on) were reported. Risk Perception and Communication, Fischhoff p1112

constrain decisions on policy developments, options etc. and on consultation and communications strategies.

USING THE FRAMEWORK

A.13 Measuring and evaluating public concern requires expertise and understanding of risk perception. Use of the framework should be proportionate to the scale of the policy initiative, the likelihood of high levels of public concern, the potential impact on the policy etc. Tools such as the Risk management ladder developed by Ortwin Renn⁴ may assist with this.

General principles

A.14 The framework provides a structure for organising and evaluating evidence of actual or potential public concern but is not prescriptive about the methods by which such evidence should be collected. **However, it is intended that the framework be used primarily as a guide for a facilitator to explore public concerns (e.g. through workshops or interviews) rather than be used as a questionnaire to elicit views directly.**

A.15 In addition to evaluating evidence using the framework structure, facilitators should also ask the public about their overall level of concern about a risk to check that the framework's output is reasonable. It is recommended that this be asked both before and after using the framework, as respondents may change their opinion after exploring the issue in detail. It may also be helpful to ask if there are any other important drivers of concern not already considered in the framework. For example, people may be concerned simply because friends or family are concerned.

Methods for engaging the public

A.16 The framework is intended primarily for structuring the evidence about public concerns. However, it could be used in a facilitated workshop, or to help elicit information using other techniques. For instance, the facilitator could explore the evidence for each indicator by asking the group about their personal views, using the prompt questions as a guide. Groups may feel that some prompts and evidence are more relevant than others, depending on the nature of the risk in question, and should be at liberty to tailor questions as appropriate. Having discussed the evidence for each indicator, groups might be able to reach a consensus on the score for that indicator. However, where there are different and irreconcilable views, the different positions should be noted.

A.17 The composition and size of facilitated groups should be appropriate to the risk under discussion. For example, it may be appropriate to elicit views of medical professionals and patient groups in discussing risks from a new type of medication. It is important that the views of all stakeholders are sought if the assessment is to be representative of public opinion. It is possible to use the framework to identify differences of views between stakeholder groupings, such as between expert and lay groups on the acceptability of risks.

A.18 Other social survey techniques may be used to collect evidence from the public about their perception of the risk. It is likely that some methods may be better suited to particular groups than others, depending on their size, availability and other needs. For

⁴ <http://greenbook.treasury.gov.uk/documents/riskmanagementladder.pdf>

example, it may be simpler to explore the views of experts through telephone or face-to-face interviews rather than a workshop. It may also be possible to develop questionnaires or surveys to explore public opinions, although this should be done with care to ensure that the data collected is representative. Social researchers and statisticians can advise on the best methods to use.

A.19 The effort expended on eliciting public opinion (including the number and size of facilitated groups) should be proportionate to the complexity of the issue and the range and strength of opinion that might be expected. In some cases, it may be sufficient to make an expert assessment of likely public opinion if time is restricted and public views are already well known (for example, because there is a history of very similar risks).

A.20 One approach⁵ to eliciting the public's views that could be adopted is briefly outlined below. The aim here is to give a flavour of the practical steps that policy makers might take (or facilitate). However, this is not the only method, nor is it a prescribed method. It is, however, a good example of a preferred method that should be considered.

1. In a series of 1:1 or group interviews, ask very open ended questions about what interviewees know about a topic;⁶
2. Prompt them to consider their understanding of 'exposure, effects and mitigation' (general risk management concepts that are unlikely to introduce any bias);
3. Ask them to elaborate further, iteratively exposing more and more levels of detail of their thinking. Review the questions in the concern assessment tool to ensure that all potential areas of concern have been covered;
4. Optionally, show respondents a set of completely random photographs, asking them to sort them according to their relevance to a topic, and to explain their reasoning as they go. This can reveal associations in the public mind that the experts may not have thought of.
5. If helpful, develop a mental map of the topic from the experts' point of view, describing the whole topic in terms of the influences on risk.

Exploring experts' concerns

A.21 The main value of expert involvement will be in making a technical assessment of risk (see Section 3). However, the framework can also be used to explore the expert's views on the nature of the hazard, potential harm and risk management. This information can be used to identify issues that need addressing, the need for further research etc. and also as a comparison with public, non-expert views. This information can help to understand any differences and assist consideration of how to address them. For example, the framework may show that whilst experts feel that the management of a particular risk is trustworthy, non-expert groups may disagree and consider the management to be untrustworthy. As a result, the non-expert group may

⁵ As discussed in Fischhoff, Bostram, Quadrel, - Risk perception and communication, in Detel, R McEwan, J, Reaglehole, R and Tanaka, H (2002), Oxford Textbook of Public Health

⁶ This can help avoid the problem of framing, whereby participants are influenced immediately by information given to them about risks, and frame their subsequent responses accordingly.

be much more concerned about the risk than the expert group and there is a need to address the trust issue.

A.22 It may also be helpful to ask experts familiar with a risk about likely public concerns before beginning public consultation. This information (along with information from experts in public behaviour) can be used to streamline the public consultation process by focusing only on the key drivers of concern from the outset. For example, experts on food risks may feel that the key driver of public concern is likely to be trust in risk management, and that this issue should be explored in detail with public groups. Similarly, for some risks one or two characteristics may have a marked influence on other characteristics in the framework (e.g. 'lack of knowledge' may have an impact on 'dread'; high levels of mistrust may impact not only on control but all other characteristics).

A.23 Finally, it may be necessary to use expert estimates of public concern (i.e. from experts in public behaviour and response) as a proxy for collecting actual public concern if an urgent policy decision is required and time is short.

INTERPRETING PUBLIC CONCERN

A.24 Research indicates that each of the six indicators is correlated with public concern; so higher scores imply a greater likely level of public concern about the risk (as discussed in Section A4). It is therefore possible to identify which factors drive the concerns of a particular group by reviewing the scores that they give to each indicator.

A.25 The framework does not attempt to integrate or aggregate scores from the six indicators into an estimate of 'total concern' because the categories are not wholly independent of each other. Moreover, the main strengths of the assessment framework are its ability to provide information on the nature of the concern and to understand how the views of different groups differ. Attempting to aggregate scores into a 'total' will lose the information on the origins of those concerns and can mask differences of opinion between stakeholders. Care should also be taken to avoid double counting where one issue clearly drives scores under several, or all, categories.

CONCERN ASSESSMENT FRAMEWORK

I. Hazard: Familiarity and Experience

These questions explore awareness and experience of a hazard. Research indicates that concern usually decreases as people become more familiar with risks and experienced in facing them. (An exception is that people may be less concerned if they are completely unaware of a risk.)

Level 1 <input type="checkbox"/>	Level 2 <input type="checkbox"/>	Level 3 <input type="checkbox"/>	Level 4 <input type="checkbox"/>	Level 5 <input type="checkbox"/>
e.g. familiarity is high across society and there is a high level of experience	e.g. most people are familiar and have direct experience of the hazard	e.g. familiarity and experience are uneven	e.g. familiarity and experience are very limited	e.g. no familiarity or previous experience – a wholly novel risk
<u>Evidence:</u> How familiar are people of the hazard? What is the extent of their experience?				
<u>Possible Management options:</u>				

How familiar are people of the hazard?

What is the extent of their experience?

- How familiar is the public with the hazard?
- Are all sections of society familiar, or is familiarity confined to specific groups?
- Are those potentially exposed to risk, familiar with it?
- Has there been previous experience of the hazard?
- Did previous experience of the hazard occur:
 - Within past year?
 - Within the past few years?
 - Within living memory?
- Was previous exposure regular/frequent or irregular/infrequent?
- Is the nature of previous experience:
 - First-hand?
 - Reported and credible?
 - Anecdotal?

2. Hazard: Understanding

These questions explore understanding of the risk's cause-effect. Research indicates that people are more concerned if they do not understand how a risk operates very well.

Level 1 <input type="checkbox"/>	Level 2 <input type="checkbox"/>	Level 3 <input type="checkbox"/>	Level 4 <input type="checkbox"/>	Level 5 <input type="checkbox"/>
e.g. understanding is widespread and detailed	e.g. basic understanding is widespread but detailed knowledge is confined to certain groups	e.g. understanding is detailed but confined to certain groups	e.g. understanding is partial and confined to certain groups	e.g. the risk is poorly understood by everyone
<u>Evidence:</u> Who understands the hazard? What do they know?				
<u>Management options:</u>				

**Who
understands
the hazard?
What do they
know?**

- Is understanding confined to certain (e.g. special interest) groups?
- Is there agreement on risk mechanisms or are there conflicting views?
- How well is the cause-effect mechanism understood?
- Is understanding, complete or partial?
- Where understanding is partial:
 - Are there similarities to existing, understood risks?
 - Are research programmes in place to deliver timely evidence?
 - Does substantial disagreement exist about fundamental aspects of the cause-effect mechanism?
 - Can the cause-effect mechanism be quantified confidently and used to predict risks accurately?
- To what extent are the effects of the risk predictable or foreseeable?
- Are risks understood sufficiently to inform risk management?

3. Effects: Equity and benefits

These questions explore how fairly risks and rewards are distributed. Research indicates that people are more concerned about risks that are perceived to be unfair, and less concerned if the benefits far outweigh their perception of risk.

Level 1 <input type="checkbox"/>	Level 2 <input type="checkbox"/>	Level 3 <input type="checkbox"/>	Level 4 <input type="checkbox"/>	Level 5 <input type="checkbox"/>
e.g. harm and rewards are distributed fairly	e.g. some suffer more than others but receive additional compensation	e.g. benefits distributed fairly, harm distributed unfairly	e.g. harm and rewards are both distributed unfairly	e.g. a small minority benefits to the extreme detriment of all others (i.e. an extremely unfair distribution)
<u>Evidence:</u> How is the risk distributed? How are the potential rewards distributed? How fairly are risk and rewards distributed?				
<u>Management options:</u>				

How is the risk distributed?

- Is potential harm distributed fairly across society?
- Are vulnerable groups affected disproportionately?
- Are the likely victims of harm known or identifiable and likely to attract sympathy?
- Are future generations likely to be affected?

How are the potential rewards distributed?

- Are potential rewards from the risk distributed fairly across society, or do some groups benefit unfairly?
- Do those who cause the risk benefit (or appear to) from it?
- Will future generations benefit from rewards?
- Are the benefits perceived to be worth the risk (and uncertainty)?
- Is there a perceived social need for the benefit?

How fairly are risk and reward distributed?

- How equally are risks and reward spread across society?
- Is this distribution perceived to be fair?
- If individual groups suffer disproportionately, do they receive additional benefit?
- Do specific groups benefit to the detriment of others?
- Is intergenerational equity maintained? Or are future generations going to be significantly affected? Will future generations be able to decide differently, or will they, as a result of our actions, have no choice?

4. Effects: Fear (Dread)

These questions explore the fear that people hold for the potential effects of a risk. Research indicates that people are more concerned about risks associated with a high degree of fear (e.g. that could cause cancer).

Level 1 <input type="checkbox"/>	Level 2 <input type="checkbox"/>	Level 3 <input type="checkbox"/>	Level 4 <input type="checkbox"/>	Level 5 <input type="checkbox"/>
e.g. effects are trivial, temporary and commonplace	e.g. effects potentially serious but treatable	e.g. effects are serious, long-term but considered natural	e.g. effects are serious, permanent and raise ethical concerns	e.g. effects are catastrophic, permanent and highly feared
Evidence: How serious are the effects? How long-term are the effects? How feared are the effects?				
Management options:				

How serious are the effects?

- How serious is the potential harm thought to be? Can it be life threatening or debilitating?
- Are the effects potentially catastrophic? (Catastrophic effects are usually more feared)
- Can many people be affected?
- Are the effects overt or hidden? (Hidden effects are usually more feared)

How long-term are the effects?

- How immediate are potential effects? (Delayed effects are usually more feared)
- Are the effects reversible?
- Will the effects be passed on to future generations?

How feared are the effects?

- Are the effects unusual or outside of normal experience?
- Is the harm feared or dreaded because it is, for example, considered abnormal or associated with great suffering?
- Are there ethical concerns? For example, are the effects perceived to be bad because they are thought of as 'unnatural'?
- Do views differ among population subgroups for religious or other reasons?
- Do the view of the exposed group differ to those of the rest of the population?

5. Management: Control

These questions explore the perceived level of control that people feel they have over a risk. Research indicates that people are more concerned about risks that they feel they cannot control.

Level 1 <input type="checkbox"/>	Level 2 <input type="checkbox"/>	Level 3 <input type="checkbox"/>	Level 4 <input type="checkbox"/>	Level 5 <input type="checkbox"/>
e.g. people feel that risks are voluntary and under their full control	e.g. people feel that risks are voluntary but then only partly under their own control	e.g. people feel that risks are imposed but then mostly under their own control	e.g. people feel that risks are imposed and are mostly out of their control	e.g. people feel that risks are imposed and are completely out of their control
<u>Evidence:</u> Do people feel that risks are voluntary? Do people feel that they can choose their level of risk?				
<u>Management options:</u>				

Do people feel that risks are voluntary?

- Do people undertake the risk knowingly?
- Do people undertake the risk voluntarily?
- If a third party imposes the risk, is it done so with informed, explicit consent?
- Is the risk escapable or inescapable?

Do people feel that they can choose their level of risk?

- Do people feel that they have enough information about a risk to manage it?
- Do they feel that they use this to take their own risk management decisions?
- Do people feel they can manage their level of exposure precisely?
- Do people feel they have the ability and resources to manage the risk themselves?
- Overall, do they people feel that they are in control of the risk they face?

6. Management: Trust

These questions explore the trust that people have in the management of risks, including the trust in the relevant science. Research indicates that people are more concerned about risks when they don't trust the people or systems that manage them.

Level 1 <input type="checkbox"/>	Level 2 <input type="checkbox"/>	Level 3 <input type="checkbox"/>	Level 4 <input type="checkbox"/>	Level 5 <input type="checkbox"/>
e.g. people know and trust the risk manager and risk creator	e.g. people don't know who manages the risk but trust 'whoever' does it	e.g. the risk manager is trusted but there are some doubts about the risk creator	e.g. people do not entirely trust the risk manager or the risk creator	e.g. people don't trust whoever manages the risk and distrust the risk creator
<u>Evidence:</u> Is the risk management system understood? Is the person managing the risk trusted? Is the person creating the risk trusted?				
<u>Management options:</u>				

Is the risk management system understood?

- Is someone appointed to manage the risk?
- Can they be identified correctly?

Is the person managing the risk trusted?

- Is the risk manager perceived to be competent and have a good track record?
- Are they perceived to act in the public interest?
- Do they involve the public and appear responsive to their concerns?
- How credible, authoritative and understandable is the information they provide?
 - Overall, can their risk management be trusted?

Is the person creating the risk trusted?

- Is the person responsible for creating the risk perceived to be generally negligent or competent in managing risks? Is the science trusted?
- Are they perceived to have a conflict of interest in managing risks (e.g. by cutting costs or maintaining profitability)?
- Do they provide information to the public, and if so how credible, authoritative and understandable is it?

B

GOVERNMENT'S PRINCIPLES OF MANAGING RISK TO THE PUBLIC

OPENNESS AND TRANSPARENCY

Government will be open and transparent about its understanding of the nature of risks to the public and about the process it is following in handling them



Government will make available its assessments of risks that affect the public, how it has reached its decisions, and how it will handle the risk. It will also do so where the development of new policies poses a potential risk to the public. When information has to be kept private, or where the approach departs from existing practice, it will explain why. Where facts are uncertain or unknown, government will seek to make clear what the gaps in its knowledge are and, where relevant, what is being done to address them. It will be open about where it has made mistakes, and what it is doing to rectify them.

INVOLVEMENT

Government will seek wide involvement of those concerned in the decision process



Government will actively involve significant stakeholders, including members of the public, throughout the risk identification, assessment and management process. This will support timely and targeted action. Two-way communication will be used in all stages of policy development, risk assessment and risk management. Where there are differences in interpretation it will aim to clarify these through open discussion, and it will seek to balance conflicting views in a way that best serves the wider public interest. It will explain how views obtained through consultation have been reflected in its decisions.

PROPORTIONALITY AND CONSISTENCY

Government will act proportionately and consistently in dealing with risks to the public



Government will base all decisions about risks on what best serves the public interest. Action taken to tackle risks to the public will be proportionate to the level of protection needed and targeted to the risk.

Government will seek to apply a consistent approach to its assessment of risks and opportunities and to its evaluation of the costs and benefits of options for handling them, and will ensure that these are clearly articulated. It will apply the precautionary principle where there is good reason to believe that irreversible harm may occur and where it is impossible to assess the risk with confidence, and will plan to revisit decisions as knowledge changes

EVIDENCE

Government will seek to base decisions on all relevant evidence



Government will aim to ensure that all relevant evidence has been considered and, where possible, quantified before it takes decisions on risk. It will seek impartial and informed advice that can be independently verified wherever possible, and seek to build a shared understanding of the risks and options for action. It will consider evidence from a range of perspectives, including the public as well as experts. It will not use the absence of evidence alone to prove the absence or presence of threat, and will acknowledge alternative interpretations of the available evidence. It will make clear how evidence has informed its decisions and will keep them under review as new evidence comes to light.

RESPONSIBILITY

Government will seek to allocate responsibility for managing risks to those best placed to control them



Government, where possible, will ensure that those who impose risks on others also bear responsibility for controlling those risks and for any consequences of inadequate control. It will aim to give individuals a choice in how to manage risks that affect them, where it is feasible and in their interest to do so and where this does not expose others to disproportionate risk or cost. It will seek to clarify where responsibility for managing risks rests and that those responsible have the authority and information to act.

CBA AND QALY APPROACHES COMPARED

C.1 The main advantages and disadvantages of these two approaches – cost benefit analysis using willingness to pay techniques, and cost effectiveness using QALYs - are set out in table 1¹.

Table 1 – Advantages and Disadvantages of CBA and CEA

Cost benefit analysis, using willingness to pay techniques to assess values	Cost effectiveness analysis, using QALYs as the output measure
<p>Advantages:</p> <p>Enables direct comparisons with costs.</p> <p>Incorporates all individual preferences, including perceptions of risk, such as ‘sense of control’.</p> <p>Enables a wide variety of options to be compared, by bringing them under a common metric</p>	<p>Advantages:</p> <p>QALY indices for a range of health conditions already exist.</p> <p>Respondents may find it easier to judge tradeoffs between health and longevity, than between health and money.</p> <p>The value of reducing mortality risk for different individuals is considered to be independent of economic circumstances (life years are counted equally regardless of personal characteristics).</p> <p>Where there are competing mortality risks, they reduce the value (in direct proportion) of mitigating a specific risk.</p> <p>QALYs remain independent of some perceptions², such as ‘sense of control’. This could be considered a disadvantage if such perceptions are important.</p>
<p>Disadvantages</p> <p>Few robust values exist which can be taken and used in appraisals of other situations.</p> <p>Some inherent difficulties in assessing tradeoffs between health and money, although recent techniques using so called ‘chained gamble’ questions have begun to overcome these earlier problems (see below).</p>	<p>Disadvantages</p> <p>People may not be indifferent to, for example, 20 years in perfect health compared to 40 years in 50% health, two scenarios yielding the same utility value.</p> <p>There is no direct comparison with other benefits.</p> <p>QALY data is not always easily obtainable in formats that can be adapted for new situations.</p>

¹ A guide to multi-criteria analysis can be found at:

http://www.odpm.gov.uk/stellent/groups/odpm_about/documents/page/odpm_about_608524.hcsp#

² Estimating QALY indices involves asking people to assess their own states of health; in that sense there is some perception.

Composition of the value of preventing a statistical fatality

C.2 The value of a prevented fatality (vpf) includes: an extrapolation from the individual's willingness to pay (wtp) for reductions in risk; the prevented loss of net output (gross output lost, less his or her lost consumption as a result of the fatality); and any ambulance and medical costs incurred. It does not contain the individuals' altruistic value for others who may suffer in an accident, but individuals' may well have included in their valuation the avoidance of suffering to friends and family that would be caused by their own fatality.

C.3 In 2002 prices, the relevant mid-point figures rounded to the nearest thousand pounds are:

Vpf = £1,250,000 =

Wtp = £1,170,000

+ Net output = £81,000 (= 430,000 – 349,000) (gross output less consumption)

+ Medical and ambulance costs < £1000

Economic models of valuations

C.4 Economic theory and empirical evidence can help to explain the differences between these two approaches in more depth. Under standard economic models, three main factors are expected principally to affect values under the willingness to pay approach:

1. **Baseline risk.** The higher the initial risk, the more people should be willing to spend to reduce risk. For instance, a 5 in 100,000 reduction in risk would be valued more highly if the baseline risk is 50 in 100,000 compared to only 10 in 100,000, despite the fact that the latter represents a 50% risk reduction compared with only 10% in the former.
2. **Absolute change in risk.** The greater the reduction in risk, the more people should be willing to pay. So people would be willing to pay more for a reduction in risk from 1 in 1,000 to 1 in 1,000,000 than merely from 1 in 1,000 to 1 in 50,000.
3. **Wealth.** Individuals will tend to value, in monetary terms, risk changes more highly if they have more income (i.e. a reflection of the ability to pay).

C.5 QALYs, as commonly applied, do not incorporate baseline risk and wealth into the calculations. The only factors that determine the QALYs gained or saved because of an intervention are:

4. Expected **change in remaining life expectancy.** This is similar to the expected change in risk. The more years expected remaining, the higher the QALY value.
5. Expected **change in health status** (or utility). The better the improvement in health status, the higher the change in the QALY; an improvement in health but with no extension to life expectancy will therefore produce a higher measure of utility.

C.6 These last two factors also affect willingness to pay valuations, but interactively. Longer life expectancy may not necessarily yield higher willingness to pay valuations, as some may, for instance, be willing to pay much to lengthen their lives by small amounts. (Someone finding out that he or she has only 1 year left to live may be willing to pay much to extend this by 6 months; potentially more so than someone with an expected 10 years left to live.)

C.7 In practice, research indicates that willingness to pay values could be affected by many other factors.

- **Fear of harm** tends to increase values - if a form of death, injury or illness is especially feared, the greater the willingness to pay. This could potentially justify a higher VPF for such risks.³
- **Old age** can also have an influence on WTP; most studies have indicated that values tend to decline significantly only with those aged over around 70 years old; but some suggest that the values do not decline as significantly.
- **Other factors** may also influence the individual's willingness to pay, some of which may relate to those listed under the factors that drive public concern (see Annex A). The factors that influence an individual's WTP could include attitudes to risk, factors specific to the risk context (such as the sense of personal control), gender, ethnicity, cultural background, household age structure and wealth, latency⁴ and levels of altruism. However, there is no agreement over how much these factors would affect willingness to pay, and in some cases it is not clear whether values would go up or down. They often interact such that it is very difficult to predict the effect using economic models and difficult or too costly to test empirically.

The chained approach⁵

C.8 The 'chained' approach to valuing health risks and outcomes can be seen as a hybrid of the WTP and QALY approaches. In its primary form (e.g. Carthy et al, 1999), it involves asking individuals to say at what point they would be indifferent between two gambles, one of which involves a health risk which is worse than that in the other. Their response is then 'chained' to their valuation of one of the health risks, which has been obtained directly, enabling their value of the second health risk to be inferred. Asking individuals to trade off gambles involving different health risks in this way is one of the approaches which has been used to estimate QALY index values, i.e. how many QALYs a given health state involves compared with full health. This leads to a more general version of the chained approach. This involves taking the existing estimated value of some health state and considering the health impacts which it is associated with, assigning to it a QALY value through reference to an existing QALY index. This gives a value of a particular size of QALY loss, and therefore implies a value for any health state with a QALY value on the same scale. The value of any other health state can then be simply inferred by assigning to it a QALY value, based on an analysis of its impact in terms of the characteristics by which the index is defined. This approach has been used in research undertaken for the Home Office to value the health impacts of violent crime (forthcoming).

³ Sunstein, C.R. (1999)

⁴ Latency – people tend to prefer to be ill later rather than sooner, so illnesses with long incubation periods tend to be discounted. The social time preference rate and its constituent elements could be used to model this.

⁵ Carthy, T, S Chilton, J Covey, L Hopkins, M Jones-Lee, G Loomes, N Pidgeon, A Spencer (1999)

Using the chained approach – an example

C.9 The EQ5D QALY index defines health states in terms of five dimensions⁶ - mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Suppose there is an existing value for preventing some health state, X, of £30,000. An estimate for a QALY value for health state X can be made by assessing where, on EQ5D, that the health state would lie if defined in terms of the same dimensions. Suppose the QALY estimate for health state X is 0.375 but health state Y has no existing value. Suppose that by defining it in terms of the same five dimensions on EQ5D it is assigned a QALY value of 0.5. This means that health state Y involves a QALY loss of 0.5 compared with 0.625 for health state X i.e. Y is the less serious health state. A value for preventing health state Y can be inferred which is $0.5/0.625 * £30000 = £24000$.

The Value of a QALY

C.10 The National Institute of Clinical Excellence currently advocates that below a most plausible incremental cost effectiveness threshold of £20,000 per QALY, judgments about the acceptability of a clinical strategy as an effective use of NHS resources are based primarily on the cost effectiveness estimate. Above this, value judgements are more likely to make more explicit reference so such factors as the degree of uncertainty surrounding the calculations, the innovative nature of the intervention, the particular features of the condition and the population receiving it, and the judgements made in previous appraisals on related technologies. Finally, above an ICER of £30,000 per QALY, the case for supporting the intervention on these factors has to be increasingly strong.⁷

C.11 There is clearly some relationship between a QALY, the value of a life year (VOLY), and the value of preventing a fatality (VPF). Research is underway to understand these relationships.

CURRENT AND RECENT RESEARCH

Cancer related fatalities

C.12 Research is now underway for the Health and Safety Executive to test the hypothesis that people would prefer more resources to be spent on the prevention of particularly 'dreaded' forms of death (such as those caused by cancer). The results of the research are expected in Autumn 2005.

Air pollution

C.13 Other research by DEFRA⁸ into the economic valuation of health benefits associated with reductions in air pollution has recently concluded. The types of ill health experienced due to air pollution vary, and the associated valuations put forward in the research, are as follows:

1. Faster ageing (chronic mortality) - due to the effect of chemicals present in the air on the body people living in areas with more pollution may age faster

⁶ Brooks, R. and the EuroQol Group (1996) 'EuroQol: The current state of play', Health Policy, 37, 53-72.

⁷ Wanless, *Securing Good Health for the Whole Population*, 2004

⁸ Valuation of health benefits associated with reductions in air pollution, DEFRA (2004)

or die younger than people in low pollution areas, perhaps leading to a shortening of life by between 1 month and 1 year for the average person.

2. Acute mortality – for some elderly people, unusually high pollution can put so much extra stress on breathing that their heart fails and they cannot expect to be revived. If the ‘bad air day’ had not happened, they could have expected to live for some more weeks or months at least, although in poor health.
3. Respiratory hospital admission – among the elderly with existing lung disease, but also those suffering from asthma or other chest conditions, who may have to be admitted to hospital for 1-14 days, perhaps followed by a period of time resting at home.
4. Days of breathing discomfort – bad air days can bring on discomfort in the chest, because of allergies, asthma or other conditions. Defra is currently preparing consultation on the Air Quality Strategy Review, which will set out proposals for figures based on the willingness to pay research for categories of impacts such as those described above. The information is expected in Autumn 2005.

Appraisal – The process of defining objectives, examining options and weighing up costs and benefits, risks and uncertainties of those options before a decision is made.

CBA – Cost benefit analysis. Analysis which quantifies in monetary terms as many of the costs and benefits of a proposal as feasible, including items for which the market does not provide a satisfactory measure of economic value.

CEA – Cost effectiveness analysis. Analysis that compares the costs of alternative ways of producing the same or similar outputs.

CUA – Cost utility analysis. Analysis that compares costs and benefits that are expressed in some measure of happiness or utility, such as QALYs.

Evaluation – Retrospective analysis of a project, programme or policy to assess how successful or otherwise it has been, and what lessons can be learnt for the future. The terms ‘policy evaluation’ and ‘post-project evaluation’ are often used to describe evaluation in these two areas.

Hazard – The potential to cause harm.

Optimism bias – The demonstrated systematic tendency for appraisers to be over-optimistic about key project parameters, including capital costs, operating costs, works duration and benefits delivery.

QALY - Quality Adjusted Life Year.

Risk – The likelihood, measured by its probability, that a particular event will occur.

VOLY – Value of a Life Year.

VOSL - Value Of a Statistical Life.

VPF – Value of Preventing a Fatality.

WTA – Willingness to Accept (The amount that someone is willing to receive or accept to give up a good or service).

WTP – Willingness To Pay (The amount that someone is willing to give up or pay to acquire a good or service).

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